Broad Agency Announcement

No. NIH-AI-2012149

Title: DEVELOPMENT OF THERAPEUTIC MEDICAL COUNTERMEASURES FOR BIODEFENSE AND EMERGING INFECTIOUS DISEASES

Issue Date: July 15, 2012

Due Date: October 1, 2012 - 3:30 p.m. Local Time

Issuing Office: Office of Acquisitions, Division of Microbiology and Infectious Diseases, DEA, NIAID, NIH, 6700-B Rockledge Drive, room 3214, MSC 7612, Bethesda, Maryland 20892-7612

Contracting Officer: Charles Jackson, Charles.Jackson@nih.gov, 301-451-3686

Contact Point/Contract Specialist: Kathy M. Fetterman, fettermanka@niaid.nih.gov, 301-402-4598

Set-Aside: No

It is requested that you send an early electronic mail message to the Contract Specialist if you intend to respond to this BAA. In your message please indicate the name of the organization, address, telephone, and include the name of the Principal Investigator, plus a short description of the scientific fields encompassed by the response.

I. INTRODUCTION

You are invited to submit a proposal in accordance with the requirements of this BROAD AGENCY ANNOUNCEMENT (BAA). The BAA is authorized by Federal Acquisition Regulation (FAR) 6.102 and further described in FAR 35.016 as well as the NIH Policy Manual, Manual Chapter 6035, Broad Agency Announcements. A BAA may be used as a solicitation mechanism for basic and applied research directed toward advancing the state-of-the-art or increasing knowledge or understanding and that part of development not related to the development of a specific system or hardware procurement. BAA's are general in nature identifying areas of research interest and shall only be used when meaningful proposals with varying technical/scientific approaches can be reasonably anticipated.

Offers submitted in response to this BAA must present detailed technical and business proposals designed to meet the Research and Technical Objectives described. The Statement of Work, including the specific technical requirements and performance specifications, is developed and proposed by the offeror, not the Government.

Proposals are NOT evaluated against each other since they are not submitted in accordance with a common Statement of Work issued by the Government. Instead, Research and

Technical Objectives are provided in the BAA that describes the research areas in which the Government is interested. Proposals received in response to the BAA are evaluated in accordance with Evaluation Factors for Award specified in Section VIII of this document.

Multiple awards are anticipated. The amount of resources made available under this BAA will depend on the quality of the proposals received and the availability of funds. The Government reserves the right to select for negotiation all, some, one, or none of the proposals received in response to this solicitation, and to make awards without discussions with proposers. The Government also reserves the right to conduct discussions if it is later determined to be necessary. Additionally, the Government reserves the right to accept proposals in their entirety or to select only portions of proposals for award.

In the event the NIAID desires to award only portions of a proposal, negotiations may be opened with that offeror. The Government reserves the right to fund proposals in phases with options for continued work at the end of one or more of the phases.

NIAID estimates that one or more contracts may be issued for an aggregate total cost (direct and indirect costs combined) of up to $18.5 million for all awards during the first non-severable phase. Awards are expected to be made on or about 06/01/2013. It is anticipated that the total costs for each award may vary depending upon the scope and capacity of the technical objectives of the award. The length of time for which funding is requested should be consistent with the nature and complexity of the proposed research. The total period of performance comprised of a base period and options proposed by an offeror should not exceed five (5) years.

II. BACKGROUND AND TECHNICAL OBJECTIVES

A. Background

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (DHHS), strive to understand, treat and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all infectious agents, with the exception of the human immunodeficiency virus (HIV). This includes basic and applied research to develop and evaluate therapeutics, vaccines, and diagnostics, which are funded through a variety of research grants and contracts. The NIAID also has a mission to advance the development of new medical countermeasures (MCM) against the biological agents that are most likely to be used in a terror attack on civilian populations.

The NIAID has been conducting and supporting much of the research and development for biodefense with defined research priority and agenda against select Category A, B, and C biothreat agents (http://www.niaid.nih.gov/topics/biodefenserelated/biodefense/research/pages/cata.aspx).

The current NIAID's Strategic Plan for Biodefense Research (http://www3.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/PDF/biosp2007.pdf) establishes a strategy for developing new and improved medical countermeasures against a broad array of biological threats, emerging and re-merging infectious diseases, including pathogens and toxins. The NIAID's plan supports the national biodefense strategy and reflects the Institute's partnerships with the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and Department of Homeland Security.

The HHS PHEMCE coordinates interagency effort aiming to optimize our preparedness for public health emergencies with respect to the creation, stockpiling, and use of medical countermeasures. Led by the Assistant Secretary for Preparedness Response (ASPR), HHS, PHEMCE consists of NIH, Food and Drug Administration (FDA), and Centers for Disease Control and Prevention (CDC), along with ex officio participation from other federal agencies. PHEMCE Implementation Plan for Threats Chemical, Biological, Radiological, and Nuclear (CBRN) (http://www.hhs.gov/aspr/barda/phemce/enterprise/strategy/index.html) sets the current priorities for medical countermeasure development against advanced, enhanced, and emerging threats and advanced agents.

B. Program Objectives

The NIAID is interested in supporting the development of promising biodefense therapeutic and prophylactic (vaccine) candidates/products with the eventual goal of stockpiling these medical countermeasures and associated technologies to protect the American public.

C. Technical Objectives

The objective of this solicitation is to support the development of candidate therapeutic products for use in post-event settings following the intentional release of the NIAID Category A, B, and C biothreat agents or in response to naturally occurring outbreaks of infectious diseases caused by the NIAID Category A, B, and C pathogens (http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/research/pages/cata.aspx). Only agents identified as the NIAID Category A, B and C Priority Pathogens are eligible as proposed candidates/products for this solicitation.

This BAA solicitation focuses on supporting the development of promising biodefense therapeutic candidates/products. One category of products being solicited are those with **broad spectrum therapeutic activity against viruses or bacterial pathogens**. This solicitation also focuses on supporting development of promising **anti-toxins** as biodefense therapeutic candidates/products, particularly small molecule therapeutics with anti-toxin activity. The research and development activities supported through this BAA will allow candidate therapeutic countermeasures to progress through the product development pipeline toward licensure by the FDA.

Broad spectrum activity is a characteristic that enables a particular product to mitigate biological threats across a range or class of agents. There are a number of traditional threats for which effective treatments are either non-existent, of limited usefulness, or vulnerable to both naturally emerging and intentionally engineered antibacterial and antiviral resistance. A limited number of anti-infectives with broad spectrum activity directed at common, invariable, and essential components of different classes of microbes could potentially be effective against both traditional and non-traditional threats. This approach would allow a small number of drugs to replace dozens of pathogen-specific drugs for emergency use. Additionally, strategies to overcome bacterial and viral drug resistance could extend the clinical utility of existing broad spectrum anti-infectives and have immediate benefits. Moreover, broad spectrum treatments directed towards host targets have the potential to be effective against one or more diseases. For instance, targeting host receptors and cellular processes to treat infections can directly prevent or treat diseases. These approaches could provide clinical utility when used alone or in combination with conventional anti-infectives.

For the purposes of this BAA, the ideal broad spectrum therapeutic candidate is defined as a single agent that meets the following three criteria/definitions:

1) A drug (synthetic or natural product) or a biological product (e.g. monoclonal antibody or a recombinant protein) intended for use in the cure, mitigation, or treatment; AND
2) A single agent with demonstrated activity in appropriate *in vitro* assays and *in vivo* models against more than one selected bacterial or viral pathogen ; AND
3) An agent that will have completed evaluation in a Phase 1 clinical trial within the 5-year contract period of performance. Phase 1 clinical trial completion is defined as completion of a Final Clinical Study Report following International Conference on Harmonization (ICH) Guidelines on Structure and Content of Clinical Study Reports E3 (http://www.pharmacontract.ch/support/su_ich_liste.htm).

Toxins are poisonous substances, especially protein, produced by living cells or organisms that are capable of causing or exacerbating disease when introduced into the body tissues. While bacteria that produce toxins may often be eliminated by the use of antibiotics during an infection, disease may still occur or may progress because of the presence of toxins produced by the pathogen. In addition, toxins may be isolated and themselves be introduced into body tissues and thereby cause disease and death, as in the case of ricin. Treatments are needed to target specific toxins in order to cure or mitigate disease caused by those toxins.

For the purposes of this BAA, the ideal anti-toxin therapeutic candidate is a single agent, preferably a small molecule, meeting the following criteria/definitions:

1) An agent intended for use in the cure, mitigation or treatment; AND
2) An agent that has demonstrated activity against a specific toxin in an *in vivo* model of disease; AND
3) An agent that will have completed evaluation in a Phase 1 clinical trial within the 5-year contract period of performance. Phase 1 clinical trial completion is defined as completion of a Final Clinical Study Report following International Conference on Harmonization (ICH) Guidelines on Structure and Content of Clinical Study Reports E3 (http://www.pharmacontract.ch/support/su_ich_liste.htm).

Therapeutics supported under this BAA are specified as the following classes:

- Broad spectrum anti-bacterial: Therapeutic with activity against one of the following bacterial pathogens: *Bacillus anthracis*, *Francisella tularensis*, *Yersinia pestis*, *Burkholderia pseudomallei*, *B. mallei*, and *Rickettsia prowazekii* **AND** in addition, activity against one other NIAID Category A, B and C bacterial threat agent.

- Broad spectrum anti-viral: Therapeutic with activity against one of the following viral pathogens: Ebola virus, Marburg virus, *Variola major*, Dengue virus, Venezuelan encephalitis virus, Western Equine encephalitis virus, and Eastern Equine encephalitis virus **AND**, in addition, activity against one other NIAID Category A, B and C viral threat agent.

- Influenza antiviral agents: Therapeutics active against multiple influenza A subtypes directed at either viral or host targets.

- Anti-toxins supported under this BAA are specified as the following: A therapeutic agent, particularly a small molecule, with activity against one of the following toxins:

Botulinum neurotoxin, Staphylococcus enterotoxin B, *Bacillus anthracis* Protective Antigen, Lethal Factor or Edema Factor, and ricin toxin.

Offerors are encouraged to apply state-of-art and innovative technological approaches and platforms in the development of the proposed candidates. State-of-art and innovative technological approaches refer to capabilities, such as temperature stabilization or delivery method, that can be engineered into a wide array of existing and candidate products to enhance the product performance. Technological platforms, on the other hand, are standardized methods that can be used to significantly reduce the time and cost required to bring medical countermeasures to licensure.

Contracts awarded under this BAA will **not** support:

- Basic research and discovery of new candidates/products.
- Refinement of a lead series to identify a lead candidate.
- Development of devices or diagnostics.
- Development of candidates/products that have not demonstrated activity in a relevant animal model of disease.

Organizations responding to this BAA will have documented expertise in product development, including regulatory submissions, to advance the development and evaluation of candidate products, against biological threats identified as NIAID Category A, B and C Priority Pathogens (http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/research/pages/cata.aspx) or Top Priority Biological Threats in the HHS, 2007 PHEMCE Implementation Plan (https://www.medicalcountermeasures.gov/BARDA/PHEMCE/enterprise/strategy/strategy.aspxhttp://www.hhs.gov/aspr/barda/phemce/enterprise/strategy/index.html) and shall complete and submit the Summary of Related Activities form from the following website (http://oamp.od.nih.gov/contracts/rfps/summact.htm).

III. GENERAL PROPOSAL INSTRUCTIONS AND INFORMATION

A. Proposal Submission

1) Receipt Date

The deadline for receipt of proposals submitted in response to this announcement is:

3:30 PM Local Time
October 1, 2012

2) Paper Copies, Discs (i.e., CD or DVD), and Online Submission

A. Paper Copies

Submit the original and 5 copies of each proposal. The Principal Investigator and a corporate official authorized to bind the offeror must sign the original. The 5 copies of the proposal may be photocopies of the original.

In addition to the paper submissions, proposers are also encouraged to submit two CD-ROM's containing a PDF (Adobe Acrobat) copy of the entire proposal (Technical and Business) and an electronic copy. This does not replace the paper copies but is in addition to them. The paper copy is the

official copy for recording timely receipt of proposals. By signing the proposal, the offeror certifies that, as part of the offer, the information in the paper copy is exactly the same as that which is contained on the electronic media.

B. Discs – Creating and Naming Files:

1. Create one PDF file of your Technical Proposal, including all attachments. The Technical Proposal should be created in a PDF format that enables word searches to the maximum extent practicable. Forms and/or documents requiring signature(s) may be scanned, but must be merged into the Technical Proposal PDF file.

2. The Business Proposal must be comprised of the following two files:

    a. The first file must be a PDF of your Business Proposal, with all attachments, including the Solicitation Section J, Attachment entitled "Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet." The Business Proposal should be created in a PDF format that enables word searches to the maximum extent practicable. Forms and/or documents requiring signature(s) may be scanned and merged into the Business Proposal PDF file.
    b. The second file must be the "Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet" in its original Excel format, not PDF.

3. A separate Disc must be submitted for the Technical Proposal and Business Proposal. *Offerors who submit both Technical and Business Proposals on the same Disc will be required to resubmit the proposals on separate Discs*.
4. Each of the proposals, Technical and Business, must be separate and complete in itself, so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other.
5. **File naming convention:** It is required that the filenames for both your Technical Proposal, Business Proposal, and Excel Workbook include the name of the offeror, the solicitation number, and the type of proposal (i.e., Technical, Business, or Excel Workbook).

    Examples:
    Technical Proposal: *XYZ Company_NIHAI2012001_Technical.pdf*
    Business Proposal: *XYZ Company_NIHAI2012001_Business.pdf*
    Excel Workbook: *XYZ Company_NIHAI2012001_Business.xlsx*

C. Online Submission of Electronic Proposals

Note: *In addition to paper copies and discs, offerors are required to submit an electronic copy of proposals online through the NIAID electronic Contract Proposal Submission (eCPS) website at:* https://ecps.niaid.nih.gov

A. eCPS PROPOSAL SUBMISSION PROCESS

1. Internet access and an email-address are required.
2. An NIH eRA Commons account is required.
3. If you do not already have an eRA Commons account, your Business Official, or authorized representative designated by your Business Official, must register for an eRA Commons account at least four weeks prior to the proposal due date. The eRA Commons Online Registration is available at https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp
4. Log into eCPS with your eRA Commons password and username to upload your proposal at: https://ecps.niaid.nih.gov
5. Follow the *"How to Submit an Electronic Proposal"* instructions provided on the eCPS website at https://ecps.niaid.nih.gov/Home/HowTo

3) Binding and Packaging of Proposal

Send all copies of a proposal in the same package. Do not use special bindings or covers. If stapled, staple the pages in the upper left corner of each proposal.

4) Contracting Officers and Addresses for Mailing or Delivery of Proposals

PAPER COPIES and CD-ROM to:

If Hand Delivery of Express Service	If Using U.S. Postal Service
Kathy Fetterman Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	Kathy Fetterman Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

In addition to the address cited above, mark each package as follows:

"BAA-NIAID-DMID-NIH-AI-2012149 TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand carried (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with FAR 15.208, Submission, Modification, Revision, and Withdrawal of Proposals and FAR 52.215-1(c)(3), Instructions to Offerors-Competitive Acquisition.

Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation.

Any proposal, modification or revision received at the offices designated below after the exact time specified for receipt is "late" and will not be considered unless it is received before award is made, and

a. There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
b. It is the only proposal received.

Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

Any and all pages of modifications or revisions to proposals that result in the proposal exceeding the stated page limitations will not be considered.

B. Formatting, Number of Copies, and Page Limitations

The Technical Proposal shall not exceed 100 single-sided pages. Pages in excess of the limitation will be deleted and will be neither read nor evaluated. Each page of the Technical Proposal must be numbered sequentially. Although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

Use your usual word processing and spreadsheet programs to prepare and format the technical and business proposals. *If documents are submitted using Adobe .pdf, the document should be submitted using a* ***.pdf searchable*** *format.*

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch on each edge of the paper.
- Print setup should be single-sided on standard letter size paper (8.5 x 11" in the U.S., A4 in Europe).

The use of links to internet web site addresses (URLs) to direct readers to alternate sources of information within the proposal are prohibited. Any links provided in a proposal will not be reviewed or considered.

Failure to adhere to the formatting requirements above may impact whether your proposal is reviewed in entirety.

Number of copies and applicable page limitations for paper copies, discs, and proposals submitted online through eCPS:

1. Total page count does not include: Title and Back Page; Table of Contents; Section Dividers that do not contain information other than title of Section.
2. Pages that are 2-sided will count as two pages.
3. Pages in excess of this limitation will be removed from the proposal and will not be considered.

NUMBER OF COPIES AND APPLICABLE PAGE LIMITATIONS

Document	Number of Copies	Page Limits
Technical Proposal	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **DISC (i.e., CD or DVD)** One (1) Disc containing one electronic copy of the Technical Proposal (including all Attachments) **ONLINE (using the eCPS website)** One (1)electronic copy of the Technical Proposal (including all Attachments)	**Not to Exceed 100 pages (inclusive of all Attachments)**
Business Proposal	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **DISC (i.e., CD or DVD)** One (1) Disc containing two files, as instructed in section II.B above. **ONLINE (using the eCPS website)** One (1) submission containing two files, as instructed below. 1. One (1) electronic PDF copy of the Business Proposal (with all Attachments including the PDF rendering of the **Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet**). 2. One (1) Electronic Cost Proposal Excel Workbook **entitled Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet to access the Excel Workbook.** Microsoft Excel 2007 version or later is required.	N/A

C. NAICS Code and Size Standard

Note: The following information is to be used by the offeror in preparing its Representations and Certifications, specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541712.
(2) The small business size standard is 500 employees.

THIS REQUIREMENT IS NOT SET ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

D. Restriction on disclosure and use of data (January 2007) – FAR 52.215-1

(1) The proposal submitted in response to this request may contain data (trade secrets; business data (e.g., commercial information, financial information, cost and pricing data); and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

"Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services (HHS), data contained in the portions of this proposal which the offeror has specifically identified by page number, paragraph, etc. as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that HHS may not be able to withhold a record (e.g. data, document, etc.) nor deny access to a record requested pursuant to the Act and that the HHS's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if HHS has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act.

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement: "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

E. Communications Prior to Contract Award

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited at the beginning of this announcement. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

F. Release of Information

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

G. Preparation Costs

This BAA does not commit the Government to pay for the preparation and submission of a proposal.

H. Promoting Efficient Spending

On September 21, 2011, the Office of Management and Budget issued Memorandum M-11-35 , entitled, "Eliminating Conference Spending and Promoting Efficiency in Government," emphasizing the President's priority to ensure that the Government operates with the utmost efficiency and eliminates unnecessary or wasteful spending. This was followed by the Executive Order on Delivering an Efficient, Effective, and Accountable Government (EO 13576) and the Executive Order on Promoting Efficient Spending (EO 13589). On January 3, 2012, the Department of Health and Human Services (DHHS) issued the memorandum "HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items, and Printing, and Publications" (See http://www.hhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html).

In support of these directives, the NIH issued a January 30, 2012, Memorandum, entitled, "NIH Guidance Related to the HHS Policies on Promoting Efficient Spending: Use of Appropriated Funds for Conferences, Conference Grants and Meetings, Food, Promotional Items, and Printing and Publications." (See http://oamp.od.nih.gov/)

Any contract awarded as a result of this solicitation will:

- Specifically prohibit the use of contract funds for the provision of food for meals, light refreshments and beverages for any NIH funded meeting or conference; and
- Limit the procurement of meeting space, promotional items, printing and publications

I. Service of Protest (September 2006) - FAR 52.233-2

(1) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Charles H. Jackson, Jr.
Contracting Officer
Office of Acquisitions
National Institute of Allergy and
Infectious Diseases
DEA, Office of Acquisitions
6700-B Rockledge Drive
Room 3156, MSC 7612
Bethesda, Maryland 20892-7612

(2) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

J. Institutional Responsibility Regarding Conflicting Interests of Investigators

45 CFR Part 94 promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed under NIH contracts will be biased by any conflicting financial interest of an Investigator. The Institution shall comply with all requirements of 45 CFR Part 94 at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=9f130b6d2d48bb73803ca91ce943be3a;rgn=div5;view=text;node=45%3A1.0.1.1.53;idno=45;cc=ecfr

K. Limitations on Use of Appropriated Funds

The Department of Health and Human Services Appropriation Act limits the use of appropriated funds on NIH grant, cooperative agreement, and contract awards as specified
below. It is anticipated that these statutory provisions will continue in subsequent fiscal years and be incorporated into any award documents. If selected for negotiations, you will be provided all specific limitations concerning appropriated funds applicable at the time of negotiations.

1) Salary Limitations

(a) Pursuant to the current and applicable HHS appropriations acts, the Contractor shall not use contract funds to pay the direct salary of an individual through this contract at a rate in excess the Federal **Executive Schedule Level II** in effect on the date an expense is incurred.

(b) For purposes of the salary rate limitation, the terms "direct salary," "salary," and "institutional base salary" have the same meaning and are collectively referred to as "direct salary" in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

Note: The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS contract or order; it merely limits the portion of that salary that may be paid with Federal funds.

(c) The salary rate limitation also applies to individuals under subcontracts. If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish contract or order funding.

(d) See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current and prior periods.

(End of clause)

See the following Web site for Executive Schedule rates of pay: http://www.opm.gov/oca/ .

(For current year rates, click on Salaries and Wages / Executive Schedule / Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages / select Another Year at the top of the page / Executive Schedule / Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

2) Restriction on Distribution of Sterile Needles

"None of the funds contained in this Act may be used to distribute any needle or syringe for the purpose of preventing the spread of blood borne pathogens in any location that has been determined by the local public health or local law enforcement authorities to be inappropriate for such distribution."

3) Restriction on Abortions

"(a) None of the funds appropriated under this Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for any abortion. (b) None of the funds appropriated in this Act, and none of the funds in any trust to which funds are appropriated in this Act, shall be expended for health benefits coverage that includes coverage of abortions. (c) The term "health benefits coverage" means the package of services covered by a managed care provider or organization pursuant to a contract or other arrangement."

4) Ban on Funding of Human Embryo Research

"(a) The Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))." The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or

more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

5) Limitation on Use of Funds for Promotion of Legalization of Controlled Substances

"(a) None of the funds made available in this Act may be used for any activity that promotes the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act except for normal and recognized executive-congressional communications. (b) The limitation in subsection (a) shall not apply when there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage."

6) Dissemination of False or Deliberately Misleading Scientific Information

"None of the funds made available in this Act may be used to disseminate scientific information that is deliberately false or misleading."

7) Restriction on Employment of Unauthorized Alien Workers

The Contractor shall not use contract funds to employ workers described in section 274A(h)(3) of the Immigration and Nationality Act, which reads as follows:

"(3) Definition of unauthorized alien.- As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

8) NIH Public Access Requirement

"The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, that the NIH shall implement the policy in a manner consistent with copyright law."

Further information on the implementation of NIH's Public Access Requirement is available in NIH Guide Notice NOT-OD-08-033 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html) published on January 11, 2008.

L. DUNS Number

Prior to award of a contract, the contractor will be required to provide a Data Universal Numbering System (DUNS) number. A DUNS number may be obtained immediately, at no charge, by calling Dun and Bradstreet at 1-866-705-5711 or via

the Internet at https://eupdate.dnb.com/requestoptions/government/ccrreg/. The contractor must also be registered in the Central Contractor Registry (CCR) prior to award of a contract. Registration can be made via the Internet at http://www.ccr.gov. If you have a DUNS number, it is recommended that the proposal provide the DUNS number.

M. Proposals must be in TWO parts

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The Technical Proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions and total cost for the work. See http://oamp.od.nih.gov/contracts/rfps/techcst5.htm. Proposals should attempt to be direct and concise in presenting information which clearly describes the proposed project. Offerors should realize that the clarity of the presentation is important in communicating their project ideas to reviewers, and that a concise and well formulated proposal is usually more effective in that respect than a voluminous proposal that lacks effective distillation of ideas.

IV. UNIFORM ASSUMPTIONS

For the purposes of estimating costs and preparing the technical proposal, the following POST-AWARD requirements will apply to all awards made under this BAA.

Offerors are instructed to address responsibility for complying with these requirements in the proposed Statement of Work for the Technical Proposal. Offerors are NOT required to submit documentation to address these post-award requirements in their technical proposals. Instructions for submitting documentation associated with post-award requirements will be provided during negotiations.

A. Audits: Assume three (3) independent audits per year for the duration of the contract period of performance.

B. Purchase of Equipment: Cost will **NOT** be allowed for the purchase of any equipment, hardware, or software under this contract.

C. Alterations and Renovations: Cost will **NOT** be allowed for any facility construction, alterations, or renovations under this contract.

D. Programmatic Presentations and Reviews

In performance of the work, offerors are expected to attend the following reviews.

1. Post Award Contract Initiation Review

In preparing the proposal, offerors should include costs for attendance at one Post Award Contract Initiation Review. Offerors should assume a one-day review will be conducted at/near Washington, D.C. or at the contractor site and attendance should include all Key Personnel and all Key Subcontractor personnel.

2. Annual Contract Reviews

In preparing the proposal, offerors should include costs for annual contract reviews. These reviews are anticipated to be held at the Contractor's facility and a location at or near Washington D.C. on an alternating-year basis. The reviews are anticipated to be one-day reviews. Offerors should include costs for the attendance of the Key Personnel, members of the External Advisory Group, and Key Subcontractor personnel.

A report of the Post Award Contract Initiation Review and Annual Contract Reviews shall be prepared by the Contractor and submitted within twenty-one (21) calendar days following the date of the reviews. These reports shall include the slide presentations and all other review materials as well as summaries of all discussions. Minutes of regular, as well as, *ad hoc* teleconferences and reviews shall be provided by the Contractor within two (2) business days following the date of the teleconference or review.

3. External Advisory Group Reviews

After contract award and in consultation with the Contracting Officer Representative (COR) and the Contracting Officer, the Contractor will establish an External Advisory Group with the relevant expertise to critically evaluate technical progress in achieving product development objectives and established timelines. It is anticipated that the External Advisory Group will consist of approximately 3-5 members. The membership of the External Advisory Group will be proposed by the Contractor and approved by the COR and Contracting Officer post-award. The specific roles and duties of the External Advisory Group members will be defined by the Contractor and approved by the COR. Compensation for this role will be provided by the Contractor with contract funds as approved by the Contracting Officer and will be commensurate with the specific roles and duties assigned to the members. The Contractor will have the External Advisory Group consulting agreements in place within six months of the effective date of the contract.

Reports of all reviews and communications with the External Advisory Group or its individual members will be documented and submitted to the COR and Contracting Officer. Documentation of such reviews/communications will be provided within twenty-one (21) calendar days and will include a summary of the discussions and copies of slide presentations.

NOTE: DO NOT identify or propose External Advisory Group members in the technical or business proposal. **Do not contact specific individuals regarding service on the External Advisory Group in advance of contract award.**

V. Reporting Requirements

In performance of the work, the following reporting requirements should be assumed:

A. Monthly Progress Report

This report shall include a description of the technical activities and results during the reporting period and the activities planned for the ensuing reporting period,

and shall include a budget summary for costs incurred during the monthly reporting period for the base period and each option and milestone. The funding level will be presented in correlation with percent completion of the activities under the base, option and/or milestone.

B. Annual Progress Report

This report includes a summation of the technical activities and results for the entire contract period covered. An Annual Progress Report will not be required for the period when the Final Report is due.

C. Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract.

In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October 2001, applies. Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

D. Final and Draft Reports

This report is to include a summation of the work performed and the results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. An annual report will not be required for the period when the Final Report is due. The Contractor shall submit, with the Final Report, a summary (not to exceed 250 words) of salient results achieved during the performance of the contract.

E. Product Development Plan and Work Plan

The Contractor shall be required to update the Product Development Plan and the Work Plan to incorporate the progress from the effective date of the contract. The Contractor shall submit an updated Product Development Plan and Work Plan for review within thirty (30) calendar days of the effective date of the contract and prior to initiation of product development activities, unless otherwise negotiated with the COR and the Contracting Officer. This updated Product Development Plan shall include:

1. Clearly defined goals, product development stages and product development activities.

2. Go/No Go decision gates.

3. Quantitative and qualitative criteria and associated data elements for assessing the scientific merit and feasibility of moving to the next stage of product development.

4. A detailed timeline for each stage covering the initiation, conduct and completion of product development activities and a budget linked to each stage. The Work Plan shall include a description of the studies to be performed within each stage of the project. The Contractor shall also be required to submit a revised Product Development Plan and associated Work Plan when a change to the approved plans is requested.

   NOTE: for purposes of this BAA:
   - **The Product Development Plan** describes the critical path and for the proposed candidate/product toward eventual licensure and identifies the decision points/gates for progress of the candidate/product.
   - The **Work Plan** describes the studies to be performed at each stage of the project within the 5 year term of award in order to implement the Product Development Plan and advance the product through phase I testing.

5. Milestone Completion/Decision Gate Report

A Decision Gate Report shall be submitted when the Contractor has completed a stage of product development and has reached a Go/No Go decision point, as defined in the Work Plan for the Implementation of the Staged Product Development Plan. These reports shall be in sufficient detail to explain comprehensively the results achieved. The description shall also include pertinent data and/or conclusions resulting from the analysis and scientific evaluation of data accumulated to date under the project. Offerors should propose the timing of these reports to coincide with the decision points specified in their SOW and workplan.

Note: Contract activities will be divided into manageable time frames with initial funding of only a Base Period. Funding of subsequent timeframes will be funded by Options. Each Option will be fully funded when exercised and will be dependent on successful completion of critical Milestones, including USG acceptance of associated deliverables when applicable. The critical predecessor activities should constitute Go/No Go criteria for successor activities. The contract budget will be aligned with the Base Period, Options and associated tasks identified in the Product Development Plan and associated Gantt Chart.

6. Audit Reports

Within thirty (30) calendar days of completion of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP or GCP guidelines, the Contractor shall provide copies of the audit report and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

7. Draft and Final Clinical Trial Protocols

The NIAID has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in the NIAID-funded clinical trials. Therefore, as described in the NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf), the Contractor shall develop a protocol for each clinical trial and submit draft protocols for review and all final protocols and protocol amendments for approval by the COR. The consultative review period for submission of draft protocols will be negotiated with the COR. The review period of final protocols will be negotiated with the COR and must occur prior to FDA submission and enrollment. An additional review and approval period may be required for changes in the final protocol. Three (3) weeks should be planned for each review period. It is recommended that protocols be submitted using the approved DMID template and include a sample Informed Consent and Clinical Trials Monitoring Plan. The DMID templates and other important information regarding performing human subject research are available at http://www3.niaid.nih.gov/research/resources/DMIDClinRsrch/.

8. Draft and Final Clinical Study Report

For each clinical study performed with contract support, a Draft Clinical Study Report shall be provided within thirty (30) calendar days of the completion of the analysis of all data generated in the clinical trial. Final Clinical Study Reports shall follow the ICH guidelines on Structure and Content of Clinical Study Reports E3 (http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationsheetsandNotices/default.htm#ich).

9. Draft and Final Animal Study Protocols

Provide electronic copies of protocols for all animal studies for review and approval to the COR at least 10 calendar days before review and finalization of the protocol unless otherwise agreed upon by the COR. The animal study protocols are expected to undergo at least one round of revision and resubmission for final approval.

10. Draft and Final Animal Efficacy Reports

For each animal efficacy study performed with contract support, a Draft Animal Efficacy Study Report should be prepared within thirty (30) calendar days, unless otherwise approved by the COR, of the completion of the analysis of all data and submitted to COR for review. A Final Animal Efficacy Study Report shall be submitted to the COR within thirty (30) calendar days of finalization of the report after the draft reports have been reviewed. At least one round of revision and resubmission for final approval is to be expected. The Animal Efficacy Study Reports shall include a complete description of the experimental design, protocol, methods, reagents, data analysis, and conclusions of studies performed to demonstrate efficacy of therapeutic product for the indication (i.e., post-exposure prophylaxis or treatment) being sought. For GLP studies the Draft and Final Animal Efficacy Study Report shall have been audited for quality assurance by the Contractor or subcontractor.

11. Copies of FDA Correspondence and Review Summaries

Submit electronic copies of the correspondence or review within five (5) business days of receiving correspondence from or holding a meeting with the FDA.

12. Human Subject IRB Annual Report (Form OMB No. 0990-0263)

Within thirty (30) calendar days of each anniversary date of the effective contract award, submit Human Subject Annual Report.

13. Invention Reporting

Electronic reporting of inventions shall be required as well as paper copies.

14. Samples of Products

The Contractor shall submit samples of non-GMP candidate therapeutics and GMP material manufactured with contract funding. The type of material and the amount will be specified in the contract.

15. Technology Transfer

Technology Transfer packages that include complete protocols and critical, assays or procedures developed and/or improved with contract funding.

16. Institutional Biosafety Approval

The Contractor shall provide documentation of materials submitted for Institutional Biosafety Committee Review and documentation of approval of experiments.

17. Other Reports

Copies of other reports for work generated under the BAA may include draft and final reports for Process Development, Assay Qualification, Assay Validation, Assay Technology Transfer, Batch Records, SOPs, Master Production Records, and Certificates of Analysis.

F. DELIVERY SCHEDULE

Delivery of other reports and deliverables will be proposed by the offerors in their technical proposal. They will be developed further after receipt of proposals as a result of finalization of the Statement of Work and other terms and conditions of any resultant contract during negotiations.

G. POST-AWARD REQUIREMENTS

Please note that the following POST-AWARD requirements will apply to all awards made under this BAA.

Offerors are instructed to address responsibility for complying with these requirements in the proposed Statement of Work for the Technical Proposal. Offerors are NOT required to submit documentation to address these post-award requirements in their technical proposals. Instructions for submitting documentation associated with post-award requirements will be provided during negotiations.

1. Clinical Protocol Implementation Requirements

   a) Contractors must develop their clinical protocols and associated documents such as the Data and Safety Monitoring Plan, in accordance with DMID standardized protocol development processes and templates (http://www3.niaid.nih.gov/research/resources/DMIDClinRsrch/) and must ensure that the clinical trial is conducted in accordance with all Federal regulations, the NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf) and, the International Conference on Harmonization ICH-E6-GCP guidelines.

   b) The clinical protocol and all protocol-related documents, including the Manual of Operations, Investigators Brochure, Case Report Forms, and informed consent documents, must be submitted to the COR for review by the appropriate NIAID staff and modified, as necessary, to accommodate recommendations resulting from such review.

c) The contractor shall be required to submit, for COR and appropriate DMID Staff to review and provide written approval of, all clinical protocols, as well as amendments and modifications to the final protocol, and protocol-related documents prior to implementation.

d) Following DMID approval of the clinical protocol, the contractor shall secure Institutional Review Board (IRB) approval and submit to the COR copies of all Essential Documentation, as defined by the ICH-E6-GCP (http://www.fda.gov/cder/guidance/959fnl.pdf), to conduct the final, COR approved, clinical trial for all participating clinical sites.

e) The contractor shall be required to submit a list of research-related Standard Operating Procedures (SOPs) that shall be used to carry out the clinical research activities.

f) Responsibility for Investigational New Drug (IND) sponsorship will be determined post-award and may rest with either the contractor or with the NIAID; the NIAID will make this determination. If an IND is held by the contractor, the contractor shall be responsible for preparing and submitting required documentation as instructed by the COR to the U.S. Food and Drug Administration (FDA) to implement the IND, e.g., providing a list of references for the study and the general investigational plan.

g) The contractor shall retain all study-related documents in compliance with regulatory requirements 2 CFR312.62(c) and 45 CFR46.115(b).

2. Contractual Commitments

Upon award of a contract, the contractor shall be required to make legal commitments through acceptance of Government contract clauses contract. The outline that follows is illustrative of the types of provisions required by the Federal Acquisition Regulations that shall be included in the contract. This is not a complete list of provisions to be included in contracts, nor does it contain specific wording of these clauses. Copies of complete terms and conditions applicable to your contract will be provided during negotiations.

a) Standards of Work. Work performed under the contract must conform to high professional standards.
b) Inspection. Work performed under the contract is subject to Government inspection and evaluation at all times.
c) Termination for Convenience. The Government may terminate the contract at any time for convenience if it deems termination to be in its best interest, in which case the contractor will be compensated for work performed and for reasonable termination costs.
d) Disputes. Any dispute concerning the contract that cannot be resolved by agreement shall be decided by the contracting officer with right of appeal.
e) Equal Opportunity. The contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin.
f) Affirmative Action for Veterans. The contractor will not discriminate against any employee or applicant for employment because he or she is a disabled veteran or veteran of the Vietnam era.
g) Affirmative Action for Handicapped. The contractor will not discriminate against any employee or applicant for employment because he or she is physically or mentally handicapped.
h) Gratuities. The Government may terminate the contract if any gratuities have been offered to any representative of the Government to secure the contract.
i) American-made Equipment and Products. When purchasing equipment or products under a contract award, the contractor shall purchase only American-made items whenever possible.
j) Examination of Records. The Comptroller General (or a duly authorized representative) shall have the right to examine any directly pertinent records of the contractor involving transactions related to this contract.
k) Default. The Government may terminate the contract for default if the contractor fails to perform the work described in the contract and such failure is not the result of excusable delays.
l) Contract Work Hours. The contractor may not require an employee to work more than eight hours a day or forty hours a week unless the employee is compensated accordingly (i.e., overtime pay).
m) Covenant Against Contingent Fees. No person or agency has been employed to solicit or secure the contract upon an understanding for compensation except bona fide employees or commercial agencies maintained by the contractor for the purpose of securing business.
n) Patent Infringement. The contractor shall report each notice or claim of patent infringement based on the performance of the contract.

3. Electronic and Information Technology (SECTION 508)

This is applicable if you are proposing EIT in your proposal:

a) Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under the resultant contract must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at http://www.section508.gov/. The complete text of Section 508 Final provisions can be accessed at http://www.access-board.gov/sec508/provisions.htm.

b) The contractor shall submit electronic reports/documents that meet the requirements of Section 508 of the Rehabilitation Act of 1973, as amended by the Workforce Investment Act of 1998. Conformance shall be verified by producing electronic reports/documents that satisfy the HHS Section 508 Checklists and Standards. (See HHS Section 508 Checklists and Standards.) For further guidance, please see http://www.hhs.gov/web/508/index.html.

VI. TECHNICAL PROPOSAL INSTRUCTIONS

It is recommended that offerors use the <u>format</u> below to prepare the Technical Proposal and present all information in the order specified.

Offerors are advised to give careful consideration to the Broad Agency Announcement Introduction, Background and Technical Objectives, all reference materials and attachments, the Technical Proposal Instructions, the Technical Evaluation Criteria, and the BAA as a whole in the development of their Technical Proposals.

In developing the proposal, offerors should include, depending on the status of the individual candidate product, the following activities:

- Identify a promising candidate/product
- Develop a Product Development Plan
- Devise a Work Plan for implementation of the Product Development Plan including milestones and gates for go/no go decisions with a timeline Gantt chart that can be correlated with a task-linked budget at a level that facilitates government oversight of funded activities.

- Carry out manufacturing and CMC development of candidate/product to optimize production, formulation and delivery
- Conduct non-clinical studies, including all Investigational New Drug (IND)-enabling studies
- Develop assays and reagents needed to support product development activities
- Develop, submit, and sponsor an Investigational New Drug application (IND) and carry out clinical trials to demonstrate product safety and/or early efficacy
- Deliver to the Government an amount, negotiated at award, of cGMP final product and all necessary supporting documentation/letters of cross-reference required for subsequent regulatory submissions, clinical trials or for any other purpose deemed necessary by the Government.

Offerors proposing subcontracts and/or consultants to perform portions of the Statement of Work should clearly identify the specific tasks for which they plan to utilize subcontractors and/or consultants, as well as the method and level of integration/coordination between the prime Contractor and all proposed subcontractors and/or consultants, and the expected advantages of such an approach. Processes for subcontractor and consultant identification, selection, management and evaluation will be described. Expected deliverables associated with consulting services will be clearly delineated.

FORMAT FOR TECHNICAL PROPOSAL

1. **PROPOSAL TITLE PAGE**. Include BAA title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or a copy.

2. **TABLE OF CONTENTS** (Each offeror's Technical Proposal shall include a Table of Contents.)

3. **OVERVIEW** (suggested 3-page maximum – included in total page limitation)

   Provide a brief description of the proposed project, including:

   A. Identification of the proposed candidate/product and brief description of product development status,
   B. Identification of any proposed technology component and a brief description of proof of concept data from animal model and other studies,
   C. A summary describing the scope of the proposed Product Development Plan,
   D. Identification of the offeror and proposed key personnel with degrees and titles,
   E. Identification of proposed subcontractors and any key subcontractor personnel with degrees and titles,
   F. A brief summary of the relative roles to be performed by the offeror and any proposed subcontractor,
   G. A brief summary of the relative roles to be performed by the offeror and any proposed subcontractor,
   H. A brief description of the facilities and other resources to be made available by the offeror and any proposed subcontractors.

4. **SCIENTIFIC AND TECHNICAL APPROACHES**

   A. **PRODUCT DEVELOPMENT PLAN**

      Technical Proposal must include a Product Development Plan that describes the critical path for the proposed candidate/product to eventual licensure and identifies the decision points/gates for progress of the candidate/product. The Product Development Plan shall include a summary of the following:

      1) A description of the candidate/product as it is currently configured.
      2) The intended use/indication of the proposed candidate/product and the biodefense/public health gap the product is intended to fill.
      3) The performance specifications and features the candidate/product should have including potential stability, dosing and safety.

4) Data to support the characterization and selection of the candidate/product for further development. A summary of the data that demonstrates activity in an appropriate animal model.

5) Discussions with FDA, if available, that is relevant to development activities for the proposed candidate/product.

6) A description of activities that are part of the critical product development path through submission of a BLA or NDA.

B. **WORK PLAN (FOR THE IMPLEMENTATION OF THE PRODUCT DEVELOPMENT PLAN)**

Technical Proposals shall include a Work Plan describing each step that the Offeror proposes to perform after contract award that is required to implement and complete all proposed work within the 5-year period of performance. The Work Plan will detail the specific tasks that the Offeror is proposing to perform with contract funding and that can reasonably be completed within the 5-year maximum period of performance. The Work Plan for the candidate/product submitted with the Technical Proposal will be subject to negotiations and if an award is made, The Statement of Work (SOW), to be developed by the offeror and provided with the Technical Proposal, shall provide for the updated Work Plan to be approved by the COR and the contracting officer prior to the initiation of any activities related to its execution. In addition, the SOW shall provide for annual updates of the Work Plan, and additional updates upon a change in any task, that must be approved by the COR and the contracting officer prior to the initiation of any activities related to its execution. The Work Plan shall include:

1) Key project objectives and defined decision points for the development of the candidate/product.

2) A detailed discussion of the proposed technical approach for each activity to be performed to achieve the key project objectives. The Work Plan shall contain sufficient detail to fully explain and justify the scientific/technical rationale for the proposed approach and/or methodologies.

3) A detailed Gantt chart organized by each specific decision gate/stage of product development proposed, as well as the overall product development program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, the date of a stated event. The timeline will identify summary tasks and subtasks, including predecessor and successor logic for all activities covering the initiation, conduct and completion of all product development activities in a base period and in subsequent option periods. The Gantt chart will be negotiated and incorporated into any resultant contract.

4) For each decision point proposed, a description of the specific qualitative and quantitative criteria and associated data elements and the process for making decisions to proceed or not proceed (Go/No-Go), for advancement of candidates/products through each stage of the product development process.

5) Plans for quality control over the implementation, coordination and conduct of the activities set forth in the Work Plan, including plans to conduct regulatory audits.

6) Approaches to integrate adverse experimental or production results, new scientific findings and/or guidance from FDA into the proposed goals and timelines. A risk management and mitigation plan is encouraged and may be required.

7) A plan for sharing data and resources, reagents, assays and animal models developed with contract funding with the scientific community.

8) A list and description of all items to be delivered to the Government at each stage in the product development process during the performance of the contract and a timeline for delivery.

9) A Technical Proposal Cost Summary to include: a list of all subcontracts by activity (For examples, GMP manufacture, IND-enabling toxicological studies, formulation and fill, etc.): a budget for each stage of product development proposed for funding (direct plus indirect).

10) The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (http://oamp.od.nih.gov/DGS/FORMS/Tech-Prop-Cost-Summ.pdf). However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

11) A task-linked budget providing a breakdown of direct costs linked to each activity, task and subtask contained on a detailed chart. The timeline shall identify summary tasks and subtasks, including predecessor and successor logic for all activities covering the initiation, conduct and completion of all product development activities in a base period and in subsequent option periods.

C. CLINICAL TRIAL PROTOCOL DEVELOPMENT AND IMPLEMENTATION

Work Plans must include:

1) A description of experience in the conduct of human subjects research in accordance with DMID, NIAID, NIH policies and guidelines or (see: http://www.niaid.nih.gov/LabsAndResources/resources/DMIDClinRsrch/Pages/default.aspx) a statement acknowledging willingness to conduct clinical research according to DMID, NIAID, NIH policies and guidelines.

2) A Protocol Synopsis for each proposed clinical trial including human subject protection, provisions for data and safety monitoring, recruitment and retention of study participants, informed consent, the quality management plan, clinical monitoring plan and the statistical analysis plan.

3) A plan that specifies at which points in the SOW it will be critical to engage in communications with the FDA and the means by which the NIAID will be kept apprised of such communications.

D. REGULATORY COMPLIANCE, QUALITY CONTROL, ASSURANCE AND DATA MANAGEMENT

1) A description of the data management and quality control systems/procedures that will be used for all studies and procedures for data entry and validation, documentation of data corrections, routine maintenance and backup, transmission of data, data

reporting and exporting system, access control and confidentiality, and data retrieval and disaster recovery.

2) A description of the statistical design and analysis resources that will be used to support contract activities.

3) A plan to develop and maintain quality assurance documentation to support adherence to FDA regulatory standards and guidance that bear on the conduct of assays under GLP, manufacturing under GMP, and performance of clinical trials under GCP standards, as relevant to the Work Plan.

4) Documentation regarding experience of the Offeror and any proposed subcontractors and consultants experience with performing regulated studies in accordance with FDA regulations and guidance, including GLP, cGMP, and/or GCP guidelines as appropriate to their proposed Statement of Work.

5) A plan to determine when audits need to be performed, timely scheduling of audits, performance of audits, and responding to audit reports.

6) An audit history of the facilities proposed for use in carrying out contract activities that will be performed under GLP, cGMP and/or GCP.

E. Letters signed by the appropriate authority allowing for pre-award site visits to the Offeror's facility and proposed subcontractors' facilities. Site visits may include GLP, cGMP, or GCP audits (as appropriate) performed by independent auditors contracted by the NIAID.

F. **FACILITIES, EQUIPMENT AND OTHER RESOURCES**

G. As appropriate, the Technical Proposal must document the availability and adequacy, including safety and security, of facilities, equipment, space, and other resources necessary for performance of the contract, including:

1) Detailed laboratory layouts.

2) Information regarding ownership/lease of the facility(ies), including documentation of the availability of proposed facilities for the duration of the contract.

3) Plans for and procedures to be utilized to insure compliance with all safety and security guidelines and regulations, including training and monitoring of personnel.

4) Plans for obtaining, adding or deleting facilities as necessary due to progress or performance issues that arise during the course of product development.

5) Document the availability of appropriate facilities for performing assays and animal studies under GLP standards, production under cGMP guidelines, and performance of clinical studies following GCP guidance.

6) Describe provisions for complying with NIH guidelines for the housing and humane care and use of laboratory animals as delineated by the Office of Laboratory Animal welfare (OLAW; http://grants.nih.gov/grants/olaw/olaw.htm).

7) Describe provisions for ensuring safe facilities and resources and for conducting work in accordance with the Biosafety in Microbiological and Biomedical Laboratories guidelines, Centers for Disease Control and Prevention and the National Institutes of Health, 4th edition, May 1999 (http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm) and interim guidelines

for influenza, 5th edition (http://www.cdc.gov/flu/h2n2bsl3.htm), as well as Department of Health and Human Services (DHHS) regulations regarding the transfer of select agents (42 CFR Part 72; http://www.cdc.gov/od/ohs/biosfty/shipregs.htm. Safety and Health HHSAR 352.223-70 clauses shall apply.

8) Describe provisions for ensuring safe facilities for the conduct of work in accordance with Recommendations for the Safe Handling of Cytotoxic Drugs, NIH Publication No. 92-2621 and the NIH Guidelines for the Laboratory use of Chemical Carcinogens, NIH Publication No. 81-2385 (http://grants2.nih.gov/grants/guide/notice-files/not92-070.html).

H. **PROJECT MANAGEMENT**

1) Describe how the project will be staffed, organized and managed, including a detailed description of the responsibilities and the level of effort for all proposed positions assigned to the contract, and an administrative framework indicating clear lines of authority and responsibility for all personnel including proposed subcontractors and consultants.

2) Describe project management systems that will be used to track activities and to keep multiple activities on time and budget.

3) Provide an Organizational Chart that delineates communication plans and line of authority within contractor and subcontractor organizations and outline the communication plan for monitoring and managing the project internally and externally and sharing information with the COR and CO.

4) Provide a plan for soliciting, evaluating, negotiating, awarding, and managing subcontracts in accordance with FAR Clause 52.244-2. e)

5) Describe experience with identification and remediation of subcontractor performance problems or noncompliance with subcontract terms and conditions.

I. **SCIENTIFIC AND TECHNICAL TEAM**

The Technical Proposal should include all information relevant to documentation of individual training, education, experience, qualifications, and expertise, as well as availability necessary for the successful completion of all contract requirements. Clearly identify who is proposed as Key Personnel. Limit CVs to 2-3 pages, provide selected references for publications relevant to the scope of this BAA, and include experience with projects of similar scope, size and complexity carried out by the offer and any proposed subcontractors over the past 5 years.

J. **ORGANIZATIONAL EXPERIENCE**

Include in the technical proposals a description of at least two examples of similar projects performed by your organization that are of comparable size and scope and/or related to the effort proposed in response to this BAA. The projects may be either completed or ongoing.

5. **STATEMENT OF WORK FORMAT**

Offeror(s) are required to provide a Statement of Work in their Technical Proposal. The Statement of Work shall be developed by each offeror and shall consist of two parts: (1) Scope and Overall Objectives, and (2) Technical Requirements. Provided below is an outline of the format that is recommended to be used by all offeror(s) in the preparation of their Statement of Work. The headers and sub-headers may be adjusted to match the requirements as proposed in each offeror's individual Technical Proposal. Offerors are reminded that this BAA is required to employ a staged or phased approach in carrying out the scope of activities defined in the proposed Statement of Work, which should be reflected in the Statement of Work design.

Contracts awarded as a result of this BAA will include the Statement of Work proposed by the offeror, as negotiated and accepted by the Government. Offeror(s) will be required to perform the activities and provide the resources appropriate to the scope of their specific negotiated Statement of Work.

The opening paragraph under the Technical Requirements section of the Statement of Work shall be followed by a description of all activities that the Contractor shall perform after the award of the contract. The Technical Requirements shall include all activities required to effectively implement the project and shall include a description of all items to be delivered to the Government during performance of the contract, such as progress reports, financial reports, end products, and other deliverables, along with a timetable for their delivery.

Each offeror shall provide detailed specifications of the requirement utilizing the following sample outline of tasks and subtasks. Any tasks or subtasks that are not applicable to your proposed effort should be deleted. Any tasks or subtasks specific to your proposed effort not addressed below shall be added.

Offerors are advised to limit the amount of proprietary data or markings in their Statement of Work. The final negotiated Statement of Work will be incorporated into the contract upon an award and may be subject to release to the public. If Statement of Work does include proprietary data or markings, offeror(s) are advised to clearly mark these portions and provide an explanation why this data/marking is proprietary.

The Offeror's proposed Statement of Work should begin as follows:

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work below:

Offerors are strongly advised to use the headings provided below in preparing the proposed Statement of Work, and to incorporate aspects of the "Work Plan for the Implementation of the Product Development Plan" as appropriate in the relevant sections of the SOW:

1. Scope and Overall Objectives

2. Technical Requirements

a. Product Development Plan

1) Non-Clinical Research and Development

2) Manufacturing and CMC Development

3) Clinical Trial Protocol Development and Implementation

b. Regulatory Compliance, Quality Control, Assurance and Data Management

c. Facilities and Other Resources

d. Project Management

e. Contract Review Meetings

f. Reports and Deliverables

6. OTHER CONSIDERATIONS

A. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (January 2006)

1. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

2. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

3. If at any time during the performance of this contract, the Contracting Officer determines, in consultation with OHRP that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and

further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Human Subject Assurances.

(End of clause)

B. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html .

The information below is a summary of the NIH Policy Announcement:

The Contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

C. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (October 2009)

1. Before undertaking performance of any contract involving animal-related activities where the species is regulated by USDA, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR sections 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

2. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

3. The Contractor agrees that the care, use and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

4. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Assurances.

   Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (E-mail: ace@aphis.usda.gov ; Web site: (http://www.aphis.usda.gov/animal_welfare).

(End of Clause)

D. SHARING RESEARCH DATA

[The data sharing plan submitted by the Contractor is acceptable/The Contractor's data sharing plan, dated TBD is hereby incorporated by reference.] The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

E. INFORMATION SECURITY REQUIREMENTS

The government will require each offeror selected for negotiations to submit an E-Authentication Risk Assessment, E-Authentication Threshold Analysis and a System Security Plan with the their Final Proposal Revision to be reviewed by the ISSO and Contracting Officer.

VII. BUSINESS PROPOSAL INSTRUCTIONS

In order to minimize the government's financial risk, contract activities will be divided into manageable time frames with initial funding of only the Base Activities. Funding of additional work will be funded by Options. Each Option will be fully funded when exercised and will be dependent on successful completion of critical predecessor activities, including USG acceptance of associated deliverables when applicable. The critical predecessor activities should constitute Go/No Go criteria for successor activities. The contract budget will be aligned with the Base Activities, Options and associated tasks identified in the proposal.

Consequently, Business Proposals must provide a detailed task-linked budget that consists of a breakdown of total costs (direct costs, indirect costs, and fees) linked to the Base period, and each Option, task and subtask contained on a detailed Gantt chart. Proposed budgets should also include an annual breakdown where annual budgets will be based on the total amount for all activities starting in that fiscal year.

A summary budget reflecting the total costs over the period of performance of the proposed contract shall be provided in the same "Breakdown of Proposed Estimated Costs (plus fee) and Labor Hours" format
http://oamp.od.nih.gov/contracts/BUSCOST.HTM)
http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls. The Gantt timeline will consist of summary tasks, tasks and subtasks, including predecessor and successor logic for all activities covering the initiation, and conduct and completion of all product development activities. Product development activities will be planned and structured such that the Base period and each individual Option will be performed within the entire period of performance of the contract. The lowest level of tasks or subtasks for each activity for which budget is assigned will be determined by the offeror. However the budget plan, based on the task-linked budget must provide for feasible execution, management and oversight. Budget linked to activities at the lowest level will include budget for all subordinate activities.

1) Certified Cost or Pricing Data

General Instructions

You must provide the following information on the first page of your pricing proposal:

a) Solicitation, contract, and/or modification number;
b) Name and address of offeror;
c) Name and telephone number of point of contact;
d) Name of contract administration office (if available);
e) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
f) Proposed cost; profit or fee; and total;
g) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;

h) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
i) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403 5(b)(1) and Table 15. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price.
j) Date of submission; and
k) Name, title and signature of authorized representative.

In submitting your proposal, you must include an index, appropriately referenced, of all the certified cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

As part of the specific information required, you must submit, with your proposal, certified cost or pricing data (as defined at FAR 2.101). You must clearly identify on your cover sheet that certified cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including;

- The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
- The nature and amount of any contingencies included in the proposed price.

You must show the relationship between contract line item prices and the total contract price. You must attach cost element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries'' section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

After final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406 2, submit a Certificate of Current Cost or Pricing Data.

2. Cost Elements

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

a) Materials and services. Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when certified cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own certified cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor certified cost or pricing data as part of your own certified cost or pricing data as required in paragraph A.2. below. These requirements also apply to all subcontractors if required to submit certified cost or pricing data.

b) Adequate Price Competition. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205 26(e)).

c) All Other. Obtain certified cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of certified cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $12.5 million or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. Also submit any information reasonably required to explain your estimating process (including the judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data, and the nature and amount of any contingencies included in the price). The Contracting Officer may require you to submit certified cost or pricing data in support of proposals in lower amounts. Subcontractor certified cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror

that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the certified cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's certified cost or pricing data is required as described in this paragraph, it must be included, along with your own certified cost or pricing data submission, as part of your own certified cost or pricing data. You must also submit any other certified cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

d) Direct Labor. Provide a time phased (e.g. monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.percentage of direct labor.

e) Indirect Costs. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

f) Other Costs. List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

g) Royalties. If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:
   1) Name and address of licensor.
   2) Date of license agreement.
   3) Patent numbers.
   4) Patent application serial numbers, or other basis on which the royalty is payable.
   5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
   6) Percentage or dollar rate of royalty per unit.
   7) Unit price of contract item.
   8) Number of units.
   9) Total dollar amount of royalties.

h) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.202 and 31.205-37).

i) Facilities Capital Cost of Money. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB CMF and show the calculation of the proposed amount (see FAR 31.205 10).

3. Formats for Submission of Line Item Summaries

The detailed breakdown shall be in the format as shown on the form Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours. For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition,

summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished. See (http://oamp.od.nih.gov/Division/DFAS/spshexcl_Updated11.2.11.xlsx)

General Information

a) There is a clear distinction between submitting certified cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of certified cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of certified cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

b) By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

4. Extent of Small Disadvantaged Business (SDB) Participation Plan.

The SDB participation will not be scored, however the Government’s conclusions about the overall commitment and realism of the offeror’s SDB Participation targets will be used in determining the relative merits of the offeror’s proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

5. Travel Costs/Travel Policy

a) Travel Costs - Commercial

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) Travel Policy

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

VIII. EVALUATION FACTORS FOR AWARD

1. GENERAL

The Government will make awards to the responsible offeror(s) whose proposals provide the best value to the Government. For this solicitation, the technical proposal shall receive paramount consideration in the selection of the contractor(s). The evaluation will be based on the demonstrated capabilities of the prospective offerors in relation to the evaluation criteria as set forth herein. Each proposal must document the feasibility of successful implementation of the requirements of the BAA.

The estimated cost of an offer must be reasonable for the tasks to be performed, and, in accordance with FAR 15.305, will be subject to a cost realism analysis by the Government.

All technical proposals will undergo evaluation by a peer review group also known as the Technical Evaluation Panel (TEP).

Final selection of awards will depend upon the technical ranking, importance to the Agency, and availability of funds and the extent of Small Disadvantaged Business Participation.

Offerors are reminded that the Technical Approach is evaluated within the context of "contribution and relevance to this program." For example, even though a proposal provides a clear, comprehensive technical plan for achieving a particular objective, if the plan is NOT within the context of the goals of this program, it will receive a low technical score regardless of the technical feasibility of the technical approach.

2. HUMAN SUBJECT EVALUATION

It is anticipated that work proposed under this announcement will involve human subjects. If your proposed work will involve human subjects, NIH Policy requires:

a. **Protection of Human Subjects from Research Risks**

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by the NIAID that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If you are invited to participate in negotiations, you will be afforded the opportunity to address the concerns raised by the reviewers and you will be able to further discuss and/or clarify your position. Once negotiations are closed, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

b. **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will consider the areas covered here in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:
    - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
    - overriding factors dictate selection of subjects); or
    - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.
- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
    - inclusion of those groups would be inappropriate with respect to their health; or
    - inclusion of those groups would be inappropriate with respect to the purpose of the research.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale

and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If you are invited to participate in negotiations, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion/exclusion of women and minorities is still found to be unacceptable, then your proposal may not be considered further for award.

c. **Children**

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Based on the reviewers' evaluation of the offeror's response, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance with NIH policy guidelines) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If you are invited to participate in negotiations, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan

for the inclusion of children is still found to be unacceptable, then your proposal may not be considered further for award.

d. **Data and Safety Monitoring**

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trials be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers will rely on the Statement of, as well as any further technical evaluation factors, for the solicitation's specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will consider the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If you are invited to participate in negotiations, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for data and safety monitoring is still found to be unacceptable, then your proposal may not be considered further for award.

3. LIVE VERTEBRATE ANIMALS EVALUATION

If you propose work involving live vertebrate animals, the proposal must include, as a separate section of the Technical Proposal titled "Vertebrate Animal Section," (VAS) a complete, concise (no more than 1-2 pages) description addressing the following five points.(See NIH Guide Notice NOT-OD-10-049 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-049.html):

a. Detailed description of the proposed use of the animals, including species, strains, ages, sex and number to be used.
b. Justification for the use of animals, choice of species, and numbers to be used.
c. Information on the veterinary care of the animals.
d. Description of procedures for minimizing discomfort, distress, pain and injury.
e. Method of euthanasia and the reasons for the selection.

As part of the overall technical evaluation of proposals, the reviewers will consider the acceptability of the offeror's description in the VAS of the technical proposal. The discussion of all five points will be addressed and evaluated. Based on the evaluation of this Section, the VAS may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the description addressing each of the five points, or no discussion can be found regarding the VAS), or "acceptable." If the reviewers find that this Section of the technical proposal is "unacceptable" they will provide a narrative supporting their findings.

If you are invited to participate in negotiations, you will be afforded the opportunity to address the concerns raised by reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed description under the VAS is still found to be unacceptable, then your proposal may not be considered further for award.

4. EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data, or, if data sharing is not possible, the offeror's documentation of its inability to share research data, shall be assessed for appropriateness and adequacy.

5. TECHNICAL EVALUATION CRITERIA:

The technical evaluation criteria are used by the peer review group when reviewing the technical proposals. As no common statement of work exists, each proposal will be evaluated on its own merits as well as with regard to its relevance to the program goals rather than against other proposals for research in the same general area. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

In considering the technical merit of each proposal, the following factors will be assessed:

TECHNICAL EVALUATION CRITERIA	WEIGHT
CRITERION 1: SCIENTIFIC MERIT AND FEASIBILITY Scientific significance, suitability, feasibility, and potential for further product development of the candidate/product including: A. The soundness, completeness and adequacy of the supporting assays and animal models data demonstrating activity of the proposed candidate/product; and B. Potential for filling a current gap and addressing a public health and biodefense need.	25

TECHNICAL EVALUATION CRITERIA	WEIGHT
CRITERION 2: MERIT OF TECHNICAL PLAN/APPROACH A. Soundness, adequacy, feasibility, completeness, and suitability of the Statement of Work. B. Soundness, adequacy, feasibility, completeness, and suitability, of the implementation plan for the Product Development as defined in the Work Plan including: 1. Adequate and quantifiable decision gates for the Go/No Go evaluation of the candidate/product as well as feasible activities to be performed within the base and option periods; 2. The clinical trial Protocol Synopsis and documented experience in performing human subjects research in accordance with Federal regulations for the conduct of clinical trials and ability to complete a Phase 1 clinical trial and the Final Clinical Study Report within the 5 year contract period; 3. The adequacy and appropriateness of the regulatory plan for entering phase I testing and eventual licensure by the FDA; 4. Proposed plans for quality control, quality assurance, and data management for the conduct of activities proposed and;. 5. Plans for modifying the Product Development Plan/Work Plan based on adverse experimental or production results, new scientific findings or regulatory guidance from FDA as well as the risk mitigation strategies for accomplishing the objectives of the contract within the period of performance.	35
CRITERION 3: SCIENTIFIC AND TECHNICAL PERSONNEL Appropriateness, adequacy and relevance of the documented education, training, experience, expertise, qualifications, and availability for the proposed scientific and technical personnel of the offeror and proposed subcontractors: A. Documented qualifications, knowledge, experience, education, competence, and availability of the PI to carry out the proposed Statement of Work and Work Plan. B. Documented qualifications, knowledge, experience, education, competence and availability of other key scientific, project management and support personnel, provided by the Contractor or by subcontractors or consultants to carry out the proposed Statement of Work and Work Plan. C. The responsibilities and level of effort of all proposed staff of the Offeror and any proposed subcontractors and consultants, including appropriate mix of staff, and expertise to carry out the proposed Statement of Work;	15

TECHNICAL EVALUATION CRITERIA	WEIGHT
CRITERION 4: FACILITIES AND INFRASTRUCTURE As required and/or appropriate for the offeror's proposed Statement of Work, documented availability, suitability, capacity and adequacy of proposed facilities, including cGMP, cGLP, aand cGCP to fulfill regulatory requirements, equipment and other resources for the development, manufacturing, preclinical testing, and clinical evaluation of the candidate/product suitable for use under IND, and the capacity of all facilities, equipment and other resources proposed to perform required testing in a timely and efficient manner including: A. Facilities and equipment for the safe and secure receipt, shipping, storage, tracking and archiving of clinical and non-clinical samples, samples for stability testing, and storage of critical reagents. B. If applicable, biocontainment facilities, safety and security procedures to conduct studies in accordance with U.S. and DHHS regulations regarding the possession, use, and transfer of Select Agents.	10
CRITERION 5: PROJECT MANAGEMENT AND ORGANIZATIONAL EXPERIENCE As required and/or appropriate for the Offeror's proposed Statement of Work, the adequacy, appropriateness, suitability, and completeness of the following: A. The Project Management Plan for overall project organization, staffing, leadership, responsibilities, management, and lines of authority, including the plan to manage the work of consultants and/or subcontractors including soliciting, evaluating, negotiating, awarding and managing any proposed subcontractor in accordance with Federal regulations to meet the overall production, non-clinical and clinical testing. B. The project management systems and quality control methods proposed to ensure the effective initiation, implementation, conduct and completion of contract activities, and to monitor, track and report on Contractor and subcontractor costs and performance.	15
TOTAL POSSIBLE POINTS	100

6. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be

evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

a. Extent to which SDB concerns are specifically identified
b. Extent of commitment to use SDB concerns
c. Complexity and variety of the work SDB concerns are to perform
d. Realism of the proposal
e. Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
f. Extent of participation of SDB concerns in terms of the value of the total acquisition

7. EVALUATION OF OPTIONS

It is anticipated that any contracts awarded from this solicitation will contain option provisions and periods.

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

8. EVALUATION OF ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY - SECTION 508

The offeror's proposal must demonstrate compliance with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194 for all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order, including EIT deliverables such as electronic documents and reports.

If your proposal does not include a completed HHS "Section 508 Product Assessment Template" (hereafter referred to as the "Template") which demonstrates that EIT products and services proposed support applicable Section 508 accessibility standards, or, if the completed "Template" included in your proposal is considered "noncompliant," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify the "Template" during discussions and in your Final Proposal Revision (FPR). If your "Template" is still considered "noncompliant" by the Government after discussions, your proposal may not be considered further for award